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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ABBOTT LABORATORIES and LABORATOIRES FOURNIER S.A.,	)	
Plaintiffs,	)	**Civil Action No. _____**
v.	)	
LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Abbott Laboratories ("Abbott") and Laboratoires Fournier S.A. ("Fournier") for their Complaint against Lupin Limited ("Lupin Ltd.") and Lupin Pharmaceuticals, Inc. ("Lupin Pharmaceuticals") (collectively "Lupin") allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent Nos. 6,277,405 ("the '405 patent"), 7,037,529 ("the '529 patent"), and 7,041,319 ("the '319 patent"). The '405, '529, and '319 patents are collectively referred to herein as the "Patents-in-Suit." This action arises out of Defendants' filing of an Abbreviated New Drug Application ("ANDA") seeking approval to sell generic copies of Plaintiffs' highly successful TRICOR® 48 mg and 145 mg products prior to the expiration of Plaintiffs' patents.

THE PARTIES

2. Plaintiff Abbott Laboratories is a corporation organized under the laws of the State of Illinois, having its headquarters and principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

3. Plaintiff Laboratoires Fournier S.A. is a French corporation having its principal place of business at 28 Boulevard Clemenceau, 21000 Dijon, France.

4. On information and belief, Lupin Ltd. is an Indian corporation having a place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (W), Mumbai 400 051, India, and having a registered office at 159 CST Road, Kalina, Santacruz (E), Mumbai 400 098, India. On information and belief, Lupin Ltd. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products through various operating subsidiaries, including Lupin Pharmaceuticals.

5. On information and belief, Lupin Pharmaceuticals is a corporation organized and existing under the laws of the Commonwealth of Virginia, having a place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland, 21202. On information and belief, Lupin Pharmaceuticals is in the business of, among other things,

manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market. Lupin Pharmaceuticals in a wholly-owned subsidiary of Lupin Ltd.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. On information and belief, this Court has personal jurisdiction over Lupin Ltd. because Lupin Ltd. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Lupin Ltd. has had persistent and continuous contacts with this judicial district, including developing and/or manufacturing pharmaceutical products that are sold in this judicial district.

8. On information and belief, this Court has personal jurisdiction over Lupin Pharmaceuticals because Lupin Pharmaceuticals has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Lupin Pharmaceuticals has had persistent and continuous contacts with this judicial district, including developing, manufacturing, and/or selling pharmaceutical products that are sold in this judicial district.

9. On information and belief, Lupin Pharmaceuticals participated in, contributed to, aided, abetted, and/or induced the submission to the United States Food and Drug Administration ("FDA") of the ANDA at issue in this case.

10. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals operate as an integrated, unitary business. For example, Lupin Ltd. includes within its Annual Report the activities of Lupin Pharmaceuticals, including revenue earned.

11. On information and belief, Lupin Pharmaceuticals is registered to do business in New Jersey.

12. On information and belief, Lupin Pharmaceuticals has appointed National Registered Agents, Inc. of Princeton, New Jersey, as its registered agent for the receipt of service of process.

13. Lupin Ltd. and Lupin Pharmaceuticals stipulated in a previous litigation to personal jurisdiction in this Court. *See* Dec. 17, 2006 Stipulation and Order, *Sepracor Inc. v. Sun Pharmaceutical Industries Ltd.*, Case No. 07-4213 (D.N.J.).

14. Two related lawsuits are currently pending in this Court. On February 29, 2008, Abbott and Fournier filed suit in the United States District Court for the Northern District of Illinois against Teva Pharmaceuticals USA, Inc. ("Teva") seeking a judgment that each of the Patents-in-Suit is infringed by Teva's filing of its ANDA No. 90-069. *See Abbott Laboratories and Laboratoires Fournier S.A. v. Teva Pharmaceuticals USA, Inc.*, Case No. 08-CV-1243 (N.D. Ill.). On November 12, 2008, the Illinois court transferred the lawsuit to this Court. On December 3, 2008, this Court acknowledged the transfer. *See Abbott Laboratories and Laboratoires Fournier S.A. v. Teva Pharmaceuticals USA, Inc.*, Case No. 08-CV-5869 (D.N.J.). On November 3, 2008, Abbott and Fournier filed suit in the United States District Court for the Northern District of Illinois against Biovail Laboratories International SRL and Biovail Corporation (collectively "Biovail") seeking a judgment that each of the Patents-in-Suit is infringed by Biovail's filing of its ANDA No. 90-715. *See Abbott Laboratories and Laboratoires Fournier S.A. v. Biovail Laboratories International SRL and Biovail Corp.*, Case No. 08-CV-6274 (N.D. Ill.). On December 10, 2008, the Illinois court transferred the lawsuit to this Court. On January 5, 2009, this Court acknowledged the transfer. *See Abbott Laboratories*

and Laboratoires Fournier S.A. v. Biovail Laboratories International SRL and Biovail Corp., Case No. 09-CV-0005 (D.N.J.).

15. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

BACKGROUND

16. Fournier is the owner by assignment of: (a) the '405 patent (attached hereto as Exhibit A); (b) the '529 patent (attached hereto as Exhibit B); and (c) the '319 patent (attached hereto as Exhibit C).

17. The '405 and '529 patents are titled "Fenofibrate Pharmaceutical Composition Having High Bioavailability and Method for Preparing It." The '319 patent is titled "Fenofibrate Pharmaceutical Composition Having High Bioavailability."

18. Abbott is the exclusive licensee of the Patents-in-Suit.

19. The Patents-in-Suit, which currently expire on January 9, 2018, each claim novel fenofibrate compositions that exhibit a particular dissolution profile.

20. Fenofibrate is useful as a lipid and cholesterol lowering agent for treatment of adults with increased triglyceride levels.

21. Abbott has approval from the FDA to market fenofibrate tablets under the name TRICOR®.

22. TRICOR® (fenofibrate) is included in the FDA's list of "Approved Drug Products With Therapeutic Equivalence Evaluations" also known as the "Orange Book." Approved drugs may be used as the basis of a later applicant's ANDA to obtain approval of the ANDA applicant's drug product under provisions of 21 U.S.C. § 355(j).

23. The FDA's "Orange Book" also lists patents associated with approved

drugs. The Patents-In-Suit are listed in the "Orange Book" in association with TRICOR® (fenofibrate).

24. On information and belief, Lupin Ltd., itself and/or through its subsidiary, agent and alter ego, Lupin Pharmaceuticals, submitted ANDA No. 90-856 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of fenofibrate tablets in 48 mg and 145 mg dosages ("Lupin's Tablets, 48 mg and 145 mg"), as generic versions of the TRICOR® 48 mg and 145 mg tablets. Upon information and belief, Lupin Pharmaceuticals will market and/or distribute Lupin's Tablets, 48 mg and 145 mg, if ANDA No. 90-856 is approved by the FDA.

25. By letter dated January 22, 2009, Lupin advised Abbott and Fournier that it had submitted ANDA No. 90-856 seeking approval to manufacture, use, or sell Lupin's Tablets, 48 mg and 145 mg, prior to the expiration of the Patents-in-Suit.

26. The January 22, 2009 letter also advised Abbott and Fournier that Lupin's ANDA included a certification under 21 U.S.C. § 355(j)(2)(vii)(IV) that, in Lupin's opinion, the Patents-in-Suit are invalid and/or will not be infringed by the commercial manufacture, use, or sale of Lupin's Tablets, 48 mg and 145 mg.

COUNT I

27. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 26 hereof, as if fully set forth herein.

28. 35 U.S.C. § 271(e)(2) provides that the submission of an application under 21 U.S.C. § 355(j) for a drug claimed in a patent or for a drug use claimed in a patent is an act of infringement if the applicant seeks FDA marketing approval effective prior to the expiration of the patent. Lupin's submission of an ANDA for approval to sell fenofibrate tablets in 48 mg and

145 mg dosages prior to the expiration of the Patents-in-Suit constitutes an act of infringement of one or more claims of each of the Patents-in-Suit under 35 U.S.C. § 271(e)(2). In addition, Lupin's Tablets, 48 mg and 145 mg infringe one or more claims of each of the Patents-in-Suit under 35 U.S.C. § 271.

29. On information and belief, Lupin acted without a reasonable basis or a good faith belief that it would not be liable for infringing the Patents-in-Suit.

30. Plaintiffs have no adequate remedy at law to redress Lupin's infringement.

31. Lupin's conduct renders this case "exceptional" as described in 35 U.S.C. § 285.

32. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the Patents-in-Suit.

PRAYER

WHEREFORE, Plaintiffs respectfully request relief and judgment as follows:

(a) a judgment that each of the Patents-in-Suit is valid and enforceable, and each of the Patents-in-Suit is infringed under 35 U.S.C. § 271(e)(2) by Lupin's filing of its ANDA No. 90-856;

(b) an order that the effective date of the approval of ANDA No. 90-856 be subsequent to the expiration date of each of the Patents-in-Suit;

(c) an injunction prohibiting Lupin from commercially manufacturing, selling or offering for sale, using, or importing the fenofibrate compositions claimed in the Patents-in-Suit or otherwise infringing one or more claims of the Patents-in-Suit;

(d) damages and/or other monetary relief pursuant to 35 U.S.C. § 284 in the event of any commercial manufacture, use or sale of fenofibrate compositions falling within the

scope of one or more claims of the Patents-in-Suit by Lupin;

(e) an award of Plaintiffs' interest, costs, reasonable attorneys' fees and such other relief as the Court deems just and proper pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and,

(f) such other and further relief as the Court may deem just and proper.

CERTIFICATION PURSUANT TO L. CIV.R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L.CIV.R. 11.2 that the matters in controversy are not the subject of any other action pending in any other court or of any pending arbitration or administrative proceeding, with the exception of the related lawsuits identified in Paragraph 14 of this Complaint involving different defendants but the same Patents-in-Suit.

Respectfully submitted,

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Dated: March 6, 2009